

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,	)	
JANSSEN, L.P., and	)	
SYNAPTECH, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 05-371-KAJ
	)	
MYLAN PHARMACEUTICALS INC.	)	
and MYLAN LABORATORIES INC.,	)	
	)	
Defendants.	)	

**JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P.,  
AND SYNAPTECH, INC.'S REPLY TO COUNTERCLAIMS**

Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs"), by their attorneys, reply to the Counterclaims of Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan") as follows:

1. The paragraphs of Mylan's Answer, Affirmative Defenses and Counterclaims that precede the heading "Counterclaims," including Paragraphs 1-35, are not part of the Counterclaims and require no response by Plaintiffs.

2. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Counterclaim Paragraph 1, and on that basis deny the allegations set forth therein.

3. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Counterclaim Paragraph 2, and on that basis deny the allegations set forth therein.

4. In response to Counterclaim Paragraph 3, Plaintiffs admit that Janssen Pharmaceutica N.V. is a corporation organized and existing under the laws of Belgium, and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

5. In response to Counterclaim Paragraph 4, Plaintiffs admit that Janssen, L.P. is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

6. In response to Counterclaim Paragraph 5, Plaintiffs admit that Synaptech, Inc. ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

7. In response to Counterclaim Paragraph 6, Plaintiffs admit that Mylan has filed counterclaims under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but deny that Mylan has stated a claim upon which relief may be granted.

8. Plaintiffs admit the allegations of Counterclaim Paragraph 7.

9. In response to Counterclaim Paragraph 8, Plaintiffs admit that this Court has personal jurisdiction over them.

10. Plaintiffs admit the allegations of Counterclaim Paragraph 9.

11. Plaintiffs admit the allegations of Counterclaim Paragraph 10.

12. In response to Counterclaim Paragraph 11, Plaintiffs admit that Synaptech is the owner of the '318 patent and that Synaptech is a proper party in this action.

13. In response to Counterclaim Paragraph 12, Plaintiffs admit that Janssen is the exclusive licensee under the '318 patent and is authorized to enforce the '318 patent.

14. In response to Counterclaim Paragraph 13, Plaintiffs admit that on June 7, 2005, Plaintiffs sued Mylan in this judicial district alleging infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A). Plaintiffs further admit that in the suit against Mylan they have sought a judgment declaring that Mylan's manufacture, use, offer for sale, or importation into the United States of the galantamine hydrobromide products for which approval is sought in ANDA No. 77-590 would constitute infringement of the '318 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

15. In response to Counterclaim Paragraph 14, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

16. Plaintiffs admit the allegations of Counterclaim Paragraph 15.

17. Plaintiffs deny the allegations of Counterclaim Paragraph 16.

18. Plaintiffs deny the allegations of Counterclaim Paragraph 17.

19. In response to Counterclaim Paragraph 18, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

20. Plaintiffs admit the allegations of Counterclaim Paragraph 19.

21. Plaintiffs deny the allegations of Counterclaim Paragraph 20.

22. Plaintiffs deny the allegations of Counterclaim Paragraph 21.

23. Plaintiffs deny that Mylan is entitled to any of the relief it has requested.

24. Any allegation not specifically admitted is denied.

25. Plaintiffs deny that Mylan is entitled to a trial by jury based on any Count in the Complaint or any Counterclaim.

**Affirmative Defense**

26. Mylan's Counterclaims are barred in whole or in part because they fail to state a cause of action upon which relief may be granted.

**Prayer For Relief**

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Mylan's Counterclaims and each and every Prayer for Relief contained therein;
- B. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims;
- D. A judgment including each and every Prayer for Relief sought by Plaintiffs in the Complaint; and
- E. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

*/s/ John G. Day*

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Dated: August 8, 2005

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 8<sup>th</sup> day of August, 2005, the attached **JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'S REPLY TO COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

Mary B. Matterer, Esquire  
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HAND DELIVERY

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VIA FEDERAL EXPRESS

*/s/ John G. Day*

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John G. Day